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VIA EMAIL

Eleanor M. Yost
Goodwin Procter LLP
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Re: Mylan Pharmaceuticals Inc. v. Yeda Research & Development Co. Ltd.
Case Nos. IPR2105-00643, IPR2015-00644 and IPR2015-00830.

Dear Eleanor:

I write regarding IPR2105-00643, IPR2015-00644 and IPR2015-00830.[1]

A. Patent Owner's Citation to Documents Not of Record

Patent Owner has not filed with the Board *any* of the materials identified in Dr. Grabowski's declaration (Ex. 2133) or identified in Dr. Grabowski's Documents Relied Upon (Ex. 2106). None of these materials are identified in Dr. Grabowski's declaration as an exhibit.

Patent Owner was required to file any exhibits it intended to rely on with the Board. 37 C.F.R. § 42.6. Accordingly, Petitioners understand that Patent Owner will not rely on any of the following materials at the oral hearing in these IPRs or Dr. Grabowski's opinions which relied thereon:

- 2015 MS Mid-Year Tracker, FINAL REPORT APPENDIX – SEPTEMBER 2015
- TEVCOP00449084–115
- TEVCOP00450191–93
- TEVCOP00451650–52
- Berndt, E. R., et al., "An Analysis of the Diffusion of New Antidepressants: Variety, Quality, and Marketing Efforts," *The Journal of Mental Health Policy and Economics*, 2002, Vol. 5, No. 1, pp. 3–19
- Cohen, J., et al., "Equivalence of Generic Glatiramer Acetate in Multiple Sclerosis: A Randomized Clinical Trial," *JAMA Neurology*, October 12, 2015

[1] These IPR proceedings were joined by IPR2015-01976, IPR2015-01980 and IPR2015-01981, respectively.

- Donohue, J. M., et al., "A Decade of Direct-to-Consumer Advertising of Prescription Drugs," *The New England Journal of Medicine*, 2007, Vol. 357, No. 7, pp. 573–681
- Leffler, K. B., "Persuasion or Information? The Economics of Prescription Drug Advertising," *J.L. & Econ.*, 1981, Vol. 24, No. 1, pp. 45–74
- Thomas, J. R., "Patent Infringement and Experimental Use Under the Hatch-Waxman Act: Current Issues," *Congressional Research Service*, 2012.
- Venkataraman, S. and Stremersch, S., "The Debate on Influencing Doctors' Decisions: Are Drug Characteristics the Missing Link?" *Management* Science, 2007, Vol. 53, No. 11, pp. 1688–1701.
- Wynn D., et al., "Patient Experience with Glatiramer Acetate 40 mg/1 mL Three-Times Weekly Treatment for Relapsing-Remitting Multiple Sclerosis: Results from the GLACIER Extension Study," *The American Academy of Neurology 2015 Annual Meeting*, Washington, D.C., April 18–25, 2015
- Biogen, "Above MS™ *Program*," available at http://www.tecfidera.com/join-biogensupport/ (last visited on 11/12/2015)
- California State Board of Pharmacy, "2015 Lawbook for Pharmacy," available at http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf (last visited on 11/16/2015)
- Copaxone® website, available at www.copaxone.com (last visited on 11/12/2015)
- Copaxone® website, "3-TIMES-A-WEEK COPAXONE® 40 MG," available at www.copaxone.com/about-copaxone/copaxone-40-mg (last visited on 11/12/2015)
- Copaxone® website, "COPAXONE® − A proven mix of efficacy, safety, and tolerability in relapsing forms of MS," available at https://www.copaxonehcp.com/about-copaxone (last visited on 11/18/2015)
- IMS Health, "Our Company," available at http://www.imshealth.com/en/about-us/ourcompany (last visited on 11/16/2015)
- National Multiple Sclerosis Society, "Definition of MS," available at http://www.nationalmssociety.org/What-is-MS/Definition-of-MS (last visited on 11/12/2015)
- National Multiple Sclerosis Society, "MS Symptoms," available at http://www.nationalmssociety.org/Symptoms-Diagnosis/MS-Symptoms (last visited on 11/12/2015)
- National Multiple Sclerosis Society, "The MS Disease-Modifying Medications," January 2015, available at http://www.nationalmssociety.org/dmd (last visited on 11/12/2015).
- National Multiple Sclerosis Society, "Types of MS," available at http://www.nationalmssociety.org/What-is-MS/Types-of-MS (last visited on 11/12/2015)
- National Multiple Sclerosis Society, "What Is MS?" available at http://www.nationalmssociety.org/What-is-MS (last visited on 11/12/2015).
- Sandoz, "GlatopaCare™," available at http://glatopa.com/glatopa_care/index.shtml (last visited on 11/12/2015)

- Sandoz, "GlatopaCare™: Co-Pay Program & Insurance and Benefits Investigation," available at http://www.glatopa.com/glatopa_care/financial_support.shtml (last visited on 11/12/2015)
- Teva, "Doctor Discussion Guide," available at https://www.copaxone.com/Resources/pdfs/DoctorDiscussionGuide.pdf (last visited on 11/12/2015)
- Teva, "Informed Treatment Decision Brochure," available at https://www.copaxone.com/Resources/pdfs/Informed_Treatment_Decision_Brochure.pdf (last visited on 11/12/2015)
- Teva, "Shared Solutions®," available at https://www.copaxone.com/Resources/pdfs/Shared_Solutions_Brochure.pdf (last visited on 11/12/2015)
- "Global BioPharmaceuticals: Game Changes in Multiple Sclerosis," *Barclays*, March 7, 2014
- "Global Biotechnology," *Credit Suisse*, April 4, 2014
- "Global Biotechnology and Pharmaceuticals – AAN 2014," *Credit Suisse*, April 30, 2014
- "Multiple Sclerosis: It's a Revolution! (vs. Evolution)," *Credit Suisse*, December 12, 2013
- "Spec Pharmaceuticals," *Morgan Stanley*, March 3, 2014
- "Teva," *Morgan Stanley*, March 14, 2014
- "Teva Pharmaceutical Industries Ltd. (TEVA)," *Citi*, February 2, 2014
- "Teva Pharmaceutical Industries Ltd. (TEVA)," *Citi*, April 4, 2014
- Aubagio® label, October 17, 2014
- Avonex® label, August 28, 2014
- Betaseron® label, September 25, 2015
- Copaxone® label, January 28, 2014
- Extavia® label, August, 14, 2009
- Gilenya® label, August 4, 2015
- Glatopa™ label, April 16, 2015
- Lemtrada® label, November 14, 2014
- Novantrone® label, March 23, 2012
- Plegridy® label, August 15, 2014
- Rebif® label, March 10, 2015
- Tecfidera® label, December 3, 2014
- Tysabri® label, May 12, 2015
- U.S. Patent No. 8,377,885
- U.S. Patent No. 8,796,226
- IMS Data Cited in Ex. 2108-2114 and 2120-2122

With regard to the IMS data cited in Exhibits 2108-2114 and 2120-2122, Patent Owner was obligated to produce the data underlying these exhibits pursuant to 37 C.F.R. § 42.65(a) and Fed.

R. Evid. 1006. Failure to produce the underlying IMS data precludes Exhibits 2108-2114 and 2120-2122 from being admitted into evidence or given any substantial weight by the Board.

B. Additional Discovery Requested by Petitioners

While Patent Owner has failed to set forth a proper evidentiary basis for its commercial success argument as purportedly set forth in the Response and in Dr. Grabowski's declaration, Petitioners are nonetheless entitled to additional discovery to rebut Dr. Grabowski's unsupported opinions. Pursuant to 37 C.F.R. §42.51(b)(2), Petitioners seek Patent Owner's agreement to produce the discovery outlined below. If agreement cannot be reached, we reserve the right to seek permission from the Board to obtain this discovery by motion.

The requested additional discovery outlined below is relevant to the issue of commercial success argued by Patent Owner in its Response and in Dr. Grabowski's declaration. This discovery is believed to be in the possession of Patent Owner or its real parties in interest, and is narrowly tailored so that it is not overly broad and/or burdensome.

In order to avoid burdening the Board with unnecessary motion practice to obtain this additional discovery, Petitioners request that by January 14, 2016 Patent Owner confirms that it will provide the requested discovery, and to provide a date on which it will do so that is well in advance of Dr. Grabowski's deposition, scheduled for January 21, 2016.

1. Promotional and Marketing Expenditures

Petitioners seek production of documents related to promotional and marketing expenditures for Copaxone 40 mg/mL and Copaxone 20 mg/mL. Specifically, Petitioners request the following additional discovery:

a. Expenditures on samples of Copaxone 40 mg/mL;

b. Expenditures on journal advertising for Copaxone 40 mg/mL;

c. Expenditures on direct-to-consumer (DTC) advertising for Copaxone 40 mg/mL; and

d. Expenditures on other marketing efforts for Copaxone 40 mg/mL; and

e. Documents sufficient to show the comparative level of promotion and marketing expenditures for Copaxone 20 mg/mL versus 20 mg/mL.

This additional discovery is issues raised by Patent Owner and its declarant, Dr. Grabowski, that the alleged commercial success is not due to the marketing and promotional activities related to

the product. *See, e.g.*, Ex. 2133 at § VI.D; *Patent Owner Response* at 58 (touting commercial success due to patented features).

Petitioners also requires this additional discovery to verify Patent Owners' statements that "[t]otal promotional marketing for Copaxone 40 mg/mL in the year that it launched was only 0.60 percent of wholesale sales, much lower than the industry average of 18 percent." Ex. 2133 at ¶56. The data presented by Dr. Grabowski is only in terms of percent of wholesale sales and does not include actual expenditure amounts. This information is believed to be in the possession of Patent Owner or its real parties in interest and Dr. Grabowski.

2. Information on Rebates, Discounts and Coupons

Petitioners seek production of documents related to any patient-directed discounts, rebates, coupons and other patient-directed financial programs, including co-pay assistance, related to Copaxone 40 mg/mL. Specifically, Petitioners request information on rebates, discounts and coupons for Copaxone 40 mg, as well as how those price discounts compare to other MS drugs.

This additional discovery is related to is issues raised by Patent Owner and its declarant, Dr. Grabowski, that the alleged commercial success is not due to the marketing and promotional activities related to the product. *See, e.g.*, Ex. 2133 at § VI.D; *Patent Owner Response* at 58 (touting commercial success due to patented features).

3. Advertising for Copaxone

Petitioners seek production of documents related to the advertising of Copaxone 20 mg/ml and Copaxone 40 mg/ml. Specifically, Petitioners request copies of advertisements (including print advertising and social media presentations) made to physicians or patients, including DTC advertising, for Copaxone 40 mg. This information was reviewed by Dr. Grabowski ("I have reviewed some marketing materials that were circulated by Teva to promote Copaxone 40 mg/mL" citing to physician brochures and marketing materials targeted at patients at ¶54) and will allow Petitioners to determine which characteristics of Copaxone 40 mg are being advertised, and whether those characteristics relate to the limitations of the challenged claims.

This additional discovery is issues raised by Patent Owner and its declarant, Dr. Grabowski, that the alleged commercial success is not due to the marketing and promotional activities related to the product. *See, e.g.*, Ex. 2133 at § VI.D; *Patent Owner Response* at 58 (touting commercial success due to patented features).

4. Documents Related to Teva's Switching Strategy

Petitioners seek production of documents related to the advertising of any efforts on behalf of Patent Owner or its real parties in interest to convert patients from Copaxone 20 mg/ml to

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